



Dear guardian of _____,

This is to notify you that your child has consented to participate in a clinical trial. The name of the study is

_____.

The purpose of this trial is _____.

He/she has given his/her consent on _____ .The trial begins on

_____ and ends on _____ . The investigator for the trial in this

unit is _____ . This trial is conducted in Finland

_____.

The person in charge of the research for this trial is _____.

Additional information is provided by _____.

According to Finnish law (*Medical Research Act No. 488/1999 and Amendment 295/2004*) a minor who has reached the age of 15 can decide to participate in a clinical trial if he/she is capable of understanding the importance of the research procedure and the research is likely to be of direct benefit to the minor's health. In such a case it is sufficient for the minor to give his/her informed consent in writing and the minor's guardian should be informed of the minor's participation in the trial. Participation in the trial is entirely voluntary and withdrawal from the trial is possible at any given moment without it affecting the participant's right to receive the necessary treatment. Prior to giving his/her consent, the child has been informed about the trial and he/she has had a sufficient amount of time to decide whether to participate in the trial.

This notification has been recorded on the participant's informed consent form.

Notification sent by: _____

Title: _____

Signature: _____

Date and place: _____

More information about paediatric clinical trials:

- FINPEDMED (Finnish Investigators Network for Pediatric Medicines): www.finpedmed.com ,
- Finnish Medicines Agency, FIMEA: http://www.laakelaitos.fi/pharma_industry/childrens_medication
- The National Advisory Board on Health Care Ethics, Sub-Committee on Medical Research Ethics; <http://www.etene.org/dokumentit/ChresEN3.pdf>